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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,971	09/30/2003	Gary K. Michelson	101.0059-02000	4939

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EXAMINER	
WILLSE, DAVID H	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,971	MICHELSON, GARY K.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Applicant's remarks have been considered. The Applicant has amended claim 41 to depend from independent claim 29 in an attempt to overcome the examiner's argument that the limitation pertaining to a *majority* of the trailing end being aligned with the anatomical curvature must be broadly interpreted because such a limitation is absent from the original disclosure (final Office action of September 13, 2005: paragraph bridging pages 3 and 4). The examiner agrees with the Applicant's observation that Figure 9 "shows an implant having a symmetrical trailing end that is configured to *conform* to the natural anatomical curvature" (Applicant's reply of March 13, 2006: page 7, lines 13-17; emphasis added). The term "conform", however, is not present in said claim limitation. A definition of "align" is "to be in or come into precise adjustment or correct relative position" (*Merriam Webster's Collegiate Dictionary*, 10th ed., 1996) and does not necessitate that the corresponding surfaces *conform*. If the Applicant were to amend the independent claims so as to effectively replace "is aligned" with --conforms--, then the examiner would be compelled to invoke a rejection under 35 U.S.C. 112, first paragraph, because "majority" (e.g., claim 29, line 14) implies a range of greater than 50%, and such a range would be unsupported by the original disclosure (MPEP § 2163.05, section III).

The examiner has withdrawn the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) based upon Brantigan, US 5,192,327. Although the sharp peaks **12b** are inherently defined by a radius (however minute or infinitesimal) and the leading ends of the ridges **12** conform to the oval (or hemi-oval) shape of the prosthesis, any resultant curved opening portions in the vertebrae are created during the insertion of the implant into the opening (column 6, lines 32-36) and hence *after* the forming step as presently claimed.

Applicant states that this application is a continuation or divisional application of the prior-filed application. A continuation or divisional application cannot include new matter.

Applicant is required to change the relationship (continuation or divisional application) to continuation-in-part because this application contains the following matter not disclosed in the prior-filed application: The sub-step of drilling the opening (claims 35 and 46) is not believed to be supported in grandparent U.S. application serial no. 09/263,266.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s) (*In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969)).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29-38, 41, 50, and 51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,241,770 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps would have been immediately obvious from patent claims 1, 10, 12, 36, and 41, for example. Forming curved openings in the vertebrae would have been obvious, for example, from patent claim 1 at column 12, lines 25-26, and from the surface roughenings on the opposed arcuate portions for engaging the adjacent vertebral bodies (patent claim 14).

Claims 29-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,485,517 B1. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the method steps would have been immediately obvious from patent claims 1, 12-14, 19, and 56, for instance.

Claims 29-38, 41, 50, and 51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/792,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps would have been immediately obvious from copending application claims 1, 10, 14, 74, 75, and so on. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 29-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/246,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps would have been immediately obvious from copending application claims 103, 107, 163, etc. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-53 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bianchi et al., US 6,033,438. As seen from Figures 8 and 9, the trailing end of the implant is configured to generally conform to at least a portion of the natural anatomical curvature of the vertebral bodies so as to locate "the structural and load bearing portion of the spacer" (column 6, lines 38-39) against the stronger bone **S** (column 6, lines 27-42). The cavity (column 3, line 42; column 17, lines 5-8) including a curved opening formed into a portion of adjacent vertebral bodies would have been inherent from the generally circular cylindrical form of the spacers and from the need to ensure sufficient load bearing and stability via threaded engagement into bone (column 6, lines 14-26; column 8, lines 5-12 and 48-51; etc.).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse
Primary Examiner
Art Unit 3738